REMARKS

In the Office Action dated December 31, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following five separate and distinct inventions:

I. Claims 1-7, 13 and 19-20, drawn to an isolated ρ-conotoxin peptide and pharmaceutical composition comprising it, classified in class 514, subclass 2.

II. Claim 8, drawn to a process of using the ρ-conotoxin peptide to test a molecule acting as an antagonist of α-1-adrenoceptor activity, classified in class 430, subclasses 7.1.

III. Claims 9-10 and 12, drawn to an isolated polynucleotide encoding a ρ-conotoxin peptide and a vector comprising the polynucleotide thereof, classified in class 536, subclass 23.1.

IV. Claim 11, drawn to an antibody against the ρ-conotoxin peptide, classified in class 530, subclass 387.1.

V. Claims 14-18 and 21-23, drawn to a method of treating a mammal by administering the isolated ρ-conotoxin peptide, classified in class 514, subclass 2.

Specifically, the Examiner alleges that Groups I, III and IV are patentably distinct from one another because the peptides of Group I, the polynucleotides of Group III and the antibody of Group IV are considered to have materially different structures. The Examiner further alleges that the compounds of each group would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use. In addition, the Examiner alleges that the polynucleotides and vectors of Group III would be searched in classes and subclasses different from the antibody of Group IV.

Furthermore, the Examiner admits that Group I is related to Group II and to Group V as product and process of use, respectively. However, the Examiner contends that Group I is

distinct from Group II and Group V are distinct because the polypeptide of Group I can be used in a process which is materially different from the process of Group II or Group V.

Moreover, the Examiner alleges that Group III are unrelated to Groups II and V, because the polynucleotide of Group III is not a composition which is involved in a process of testing a molecule (Group II) or a composition which is involved in a method of treating a disease state (Group V). Similarly, the Examiner alleges that Group IV is unrelated to Groups II and V, because the antibody of Group IV is not a composition which is involved in a process of testing a molecule (Group II) or a composition which is involved in a method of treating a disease state (Group V).

In addition, the Examiner alleges that Groups II and V are directed to different and distinct methods because they involve different steps, starting material, objectives, technical considerations, ingredients, endpoints and/or treatment outcomes.

The Examiner further indicates that, where Applicant elects claims directed to a product and a product claim is subsequently found allowable, process claims that have been withdrawn and depend from the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. In order to retain the right to rejoinder in accordance with the above policy, the Examiner has recommended that the process claims be amended to depend on the product claims or to otherwise include the limitations of the product claims.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-7, 13 and 19-20, drawn to an isolated ρ-conotoxin peptide and pharmaceutical compositions comprising the peptide. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

In addition, to reserve the right to rejoinder of process claims, Applicants have amended the claims of Group V to depend from claim 1. Applicants further submit that the claims of Group II-IV already depend from claim 1.

However, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

In the first instance, Applicants observe that the present application is the national phase of an international application. Therefore, the Examiner is required under Article 27 and Rule 13 of PCT, and MPEP §1893.03(d), to follow the Unity of Invention standard as set forth in 37 C.F.R. §1.475.

The first sentence of 37 C.F.R. §1.475(a) states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) It is further stated in 37 C.F.R. §1.475(a) that "[t]he expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

Applicants respectfully submit that Groups I-V are linked to each other under a single general inventive concept. Specifically, the present invention provides novel peptides of Group I, useful as selective α1-adrenoceptor antagonists. The polynucleotides of Group III encode the peptides of Group I and can be used to make the peptides of Group I. The antibodies of Group IV are directed against the peptides of Group I and thus can be used to detect or purify the peptides of Group I. The methods of Group II and V are simply directed to uses of the peptides of Group I. Clearly, Groups I-V relate to different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Furthermore, Applicants respectfully submit that §1.475(b)(3) specifically considers "a product, a process specifically adapted for manufacture of said product and a use of said product" to have unity of invention. Therefore, it is respectfully submitted that the peptides of Group I, the polynucleotides and antibodies of Groups III and IV which are specifically for the manufacture of the peptides of Group I, and the methods of using the peptides (Groups II and V), have unity of invention and should be examined in one application.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as

evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

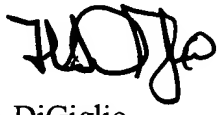
All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the

Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined five groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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